50 of this chapter. Such a study is also subject to the requirements for institutional review under part 56 of this chapter, unless exempt under §56.104 or §56.105.

[47 FR 44071, Oct. 5, 1982]

Subpart D—Licensing of Foreign Establishments and Products

§ 601.30 Licenses required; products for controlled investigation only.

Any biological or trivalent organic arsenical manufactured in any foreign country and intended for sale, barter, or exchange shall be refused entry by collectors of customs unless manufactured in an establishment holding an unsuspended and unrevoked establishment license and license for the product. Unlicensed products that are not imported for sale, barter, or exchange and that are intended solely for purposes of controlled investigation are admissible only if the investigation is conducted in accordance with section 505 of the Federal Food, Drug, and Cosmetic Act and the requirements set forth in parts 50, 56 unless exempted under §56.104 as granted a waiver under §56.105, parts 58 and 312 of this chapter.

[46 FR 8956, Jan. 27, 1981]

§ 601.31 Procedure.

Except as otherwise provided in this subchapter, licenses for foreign establishments and products shall be issued, suspended, and revoked in the same manner as licenses for domestic establishments and products. Each foreign establishment holding a license and sending, carrying, or bringing any licensed product into any State or possession for sale, barter, or exchange shall file with the Director, Center for Biologics Evaluation and Research, the name and address of each person to whom such a product is thus sent, carried, or brought. Foreign licensees shall notify each person in the United States to whom such a product is thus sent, carried, or brought, to keep such records of distribution as are required of domestic licensed establishments. Failure to give such notice to maintain records shall constitute ground for revocation of license.

[38 FR 32052, Nov. 20, 1973, as amended at 49 FR 23833, June 8, 1984; 55 FR 11013, Mar. 26, 1990]

§ 601.32 Form of license.

Licenses for establishments located in foreign countries shall be in form similar to that for domestic establishments except that they shall authorize manufacture for sending, carrying, or bringing for sale, barter or exchange from the foreign country designated in the license into any State or possession of the United States and shall specify that it is issued upon the condition that the licensee will permit the inspection during all reasonable hours of the establishment by any officer, agent, or employee of the Department of Health and Human Services authorized by the Secretary for such purpose.

§ 601.33 Samples for each importation.

Random samples of each importation, obtained by the District Director of Customs and forwarded to the Director, Center for Biologics Evaluation and Research, shall be at least two final containers of each lot of product. A copy of the associated documents which describe and identify the shipment shall accompany the shipment for forwarding with the samples to the Director, Center for Biologics Evaluation and Research. For shipments of 20 or less final containers, samples need not be forwarded, provided a copy of an official release from the Center for Biologics Evaluation and Research accompanies each shipment.

[38 FR 32052, Nov. 20, 1973, as amended at 49 FR 23833, June 8, 1984; 55 FR 11013, Mar. 26, 1990]

Subpart E—Accelerated Approval of Biological Products for Serious or Life-Threatening Illnesses

SOURCE: 57 FR 58959, Dec. 11, 1992, unless otherwise noted.

§ 601.40 Scope.

This subpart applies to certain biological products that have been studied for their safety and effectiveness in